



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/980,134

07/02/2002

Raghuveer Basude

DRE-0063

8214

26259

7590

06/10/2005

LICATLA & TYRRELL P.C.

66 E. MAIN STREET

MARLTON, NJ 08053

EXAMINER

HARTLEY, MICHAEL G

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,134

Applicant(s)

BASUDE ET AL.

Examiner

Michael G. Hartley

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/3/2005 has been entered.

Response to Amendment

The amendment filed 5/03/2005 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 10-14 rejected under 35 U.S.C. 102(b) as being anticipated by Rasor (US 5,141,738), for the reasons set forth in the office action mailed 5/13/2004.

Applicant's arguments filed 5/03/2005 have been fully considered but they are not persuasive.

Applicant asserts that, in contrast to the microbubbles disclosed by Rasor, the microbubbles of the instant invention were prepared without the use of surfactant.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the microbubbles are prepared without surfactant) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant's assertions that the use of "consisting essentially of" excludes that the use of surfactant in making the microbubbles is unclear and unseen. The "consisting essentially of" terminology in the claims limits the stabilized microbubbles to include a microparticle and a gas microbubble. However, since a surfactant is often an integral part of a gas microbubble, as shown by both Rasor and Schneider, the term "microbubble" cannot be used to exclude surfactant. For example, a claim drawn to "consisting essentially of a car" would not exclude a car radio, which may or may not be present in a car (but usually is present). This is the same with gas microbubbles, which often contain surfactant, as shown by the prior art. Therefore, the term "consisting essentially of...a gas microbubble" in no way excludes surfactant, as asserted. Further, the microparticles of the invention clearly contain a surfactant and are part of the microbubbles as claimed. Note, the claimed microbubbles "consist essentially of" both microparticles and gas microbubbles. Thus, it is unclear how this recitation would exclude surfactant from either the microparticles or gas microbubble or just from gas microbubble, as appears to be asserted. Further, note in columns 5-6 of Rasor, that the microbubble are formed by dispersion in water and therefore it is the microparticles which stabilize the gas bubbles of Rasor that contain the surfactant and not the gas microbubbles themselves. This is the same as is asserted is being claimed.

Claims 1-7 and 9-14 rejected under 35 U.S.C. 102(b) as being anticipated by Schneider (US 5,271,928), for the reasons set forth in the office action mailed 5/13/2004.

Applicant's arguments filed 5/03/2005 have been fully considered but they are not persuasive.

Applicant makes the same assertion for Schneider as made of Rasor above, that the instant claims exclude making the claimed stabilized microbubbles with a surfactant.

As stated above, the claims are not limited to exclusion of a surfactant in making the claimed microbubbles. First, this exclusion is not in the claims. Second, this assertion appears to contradict the definition of gas microbubble as known in the art. Third, the assertion appears to contradict the actual invention, which uses a surfactant in the microparticles that stabilize the gas microbubbles. The term "consisting essentially of" in the preamble of the claim cannot be used to specifically exclude something from one component in a claim while allowing it in another (i.e., excluding from the gas microbubbles but

not the microparticles that stabilize the microbubbles). Further, the surfactants used in Schneider are used in the liposomes which are used to stabilize the gas bubbles that do not contain surfactant, which is the same as is asserted is being claimed. It is noted some of the dependent claims are product-by process claims, which are examined as reading on the product. Also, the process in these claims is open-ended which recite comprising in the listed steps.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rasor (5,141,738) or Schneider (5,271,928) in view of Unger (US 5,542,935), for the reasons set forth in the office action mailed 5/13/2004.

Applicant's arguments filed 5/03/2005 have been fully considered but they are not persuasive.

Applicant asserts that Rasor and Schneider use a surfactant in their microbubble compositions which is excluded from the claimed compositions and that Unger fails to remedy this deficiency.

This is not found persuasive because, for the reasons set forth above under the 102 rejections, Rasor and Schneider. The instant claims do not exclude the use of a surfactant. Further, Unger is relied on for teaching the use of ultrasound to rupture particles for releasing drug.

Conclusion

No claims are allowed at this time.

This is a RCE of applicant's earlier Application No. 09/980,134. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of

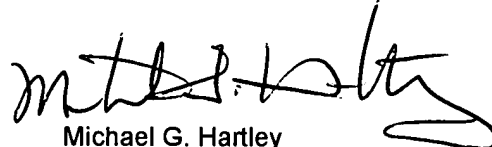
record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-Tu and Th-F, 7:30-4, Telework on Wed..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael G. Hartley
Primary Examiner
Art Unit 1618

6/8/2005